



ENZYMATIC THERAPY

What **Better** feels like.™

July 11, 2005

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 810
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Remifemin works safely and effectively to treat menopause symptoms without affecting hormone levels or vaginal cytology (pap smear).*	Black Cohosh (Root and Rhizome)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 7/11/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer

INTEGRATIVE THERAPEUTICS INC.™

NF Formulas PhytoPharmica
Tyler Encapsulations Vitaline Formulas

9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 F: 503.582.0467

ENZYMATIC THERAPY®

&
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

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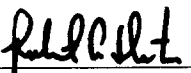
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Remifemin decreases the physical symptoms of menopause by approximately 60% (Kupperman Menopausal Index).*	Black Cohosh (Root and Rhizome)

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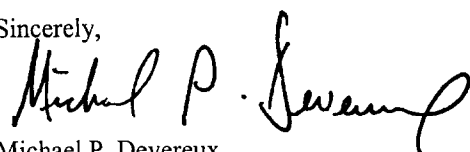
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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date 7/11/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Daily hot flashes decreased by 86% in the Remifemin group (from 4.9 to 0.7 per day.)* Emotional complaints were also dramatically reduced.*	Black Cohosh (Root and Rhizome)

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Date _____

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Remifemin effectively relieved menopausal symptoms, particularly in women in the early stage of menopause.* Most significant reduction was in hot flash occurrence.* Other symptoms resulting in significant reduction include; psyche (irritability and memory), and atrophy (vaginal dryness).*	Black Cohosh (Root and Rhizome)

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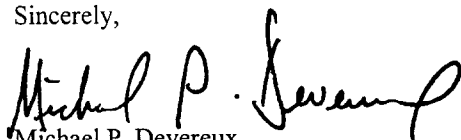
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	Remifemin reduced mean daily hot flash frequency by 50% after 4 weeks.* Overall, participants reported less trouble with sleep, less fatigue, and fewer night sweats.*	Black Cohosh (Root and Rhizome)

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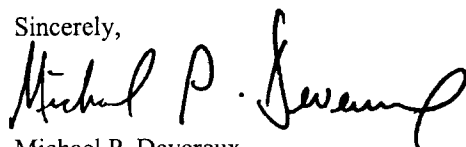
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Remifemin®	No estrogen stimulating effects were found.*	Black Cohosh (Root and Rhizome)

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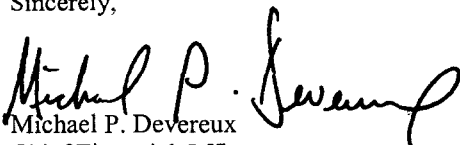
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